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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NELSON J. WRIGHT and LAURENCE J. NEWELL

Appeal 2009-003286 Application 10/750,164 Technology Center 3700

Decided: November 20, 2009

Before TONI R. SCHEINER, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal by the Patent Applicants from the Patent Examiner's rejection of claims 1-15 under 35 U.S.C. § 103(a). Jurisdiction for this appeal is under 35 U.S.C. § 6(b). We reverse.

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¹ Heard Oct. 21, 2009.

STATEMENT OF THE CASE

"Implantable markers have been used to identify locations within objects, such as a human body. For example, a marker may be implanted in a patient within an organ of interest. As the patient moves, the marker can be used to track the location of the organ." (Spec. 1). "[O]ne technique for locating a marker is by measuring the magnetic flux generated by the marker upon excitation from a source." (*Id.*) "The system . . . may be used with guided radiation therapy to accurately locate and track a target in a body to which guided radiation therapy is delivered." (*Id.* at 4.) "Because of the toxic nature of the radiation, it is important to precisely and accurately focus the radiation onto the desired site." (*Id.*) The marker acts as a "guide point" for the radiation therapy. (*Id.*)

The claims are drawn to a receiver apparatus for receiving and processing input signals from a marker emitting a magnetic flux (claim 1) and also to methods of using the receiver (claims 6 and 11). The receiver is for discarding marker signal inputs received in the presence of interfering radiation from the radiation delivery source.

Claims 1-15 are pending and stand rejected as follows:

- Claims 1, 2, 4-7, 9-12, 14, and 15 under 35 U.S.C. § 103(a) as obvious over Mate (US Published Application 2002/0193685 A1, published Dec. 19, 2002) (Ans. 3); and
- Claims 3, 8, and 13 under 35 U.S.C. § 103(a) as obvious over Mate and Acker (US Patent 5,729,129, issued Mar. 17, 1998) (Ans. 4).

Claims 1 and 11 are representative and read as follows:

1. A receiver that receives a plurality of inputs indicative of a sensed magnetic flux induced by a marker, said marker excited by an excitation source, said receiver comprising:

a sensor configured to receive a plurality of inputs; a correlation processor for analyzing said plurality of inputs in a coherent manner and for generating a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs, wherein inputs that are acquired when a therapeutic radiation source is active are considered corrupted.

11. A method of irradiating a patient with radiation from a therapeutic radiation source, said radiation targeted by the use of a marker associated into said patient, the method comprising:

applying an excitation to said marker using an excitation source;

using a receiver to receive a plurality of inputs indicative of a sensed magnetic flux induced by said marker in response to said excitation;

discarding corrupted inputs subject to interference from said therapeutic radiation source from said plurality of inputs to create a subset of said plurality of inputs; and

using a processor to perform an analysis on said subset to locate said marker.

OBVIOUSNESS OVER MATE

Claims 1, 2, 4-7, 9-12, 14, and 15 stand rejected under 35 U.S.C. § 103(a) as obvious over Mate (Ans. 3).

Statement of the Issue

Claim 11 is to a method claim of irradiating a patient with radiation from a therapeutic source. The method involves:

- 1) "applying" excitation to a marker using an "excitation source";
- 2) "using a receiver to receive" inputs from magnetic flux induced by the marker in response to the excitation;
- 3) "discarding corrupted inputs subject to interference from said therapeutic radiation source from said plurality of inputs to create a subset of said plurality of inputs"; and

4) analyzing the subset of inputs to locate the marker.

Claim 1 is to a receiver that performs the same function recited in steps 2 and 3 of claim 11.

Claim 1 requires that the receiver comprises a "correlation processor." The processor is for:

analyzing said plurality of inputs in a coherent manner and for generating a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs, wherein inputs that are acquired when a therapeutic radiation source is active are considered corrupted.

Thus, in claims 11 (step 3) and 1 (the "correlation processor") certain inputs received by a receiver are discarded when subjected to interference by a therapeutic radiation source. The discarded inputs are said to be "corrupted" by the therapeutic radiation source when the latter is on at the same time as the magnetic flux emitted by the marker. The remaining inputs represent a "subset" of the inputs received by the receiver.

The Examiner found that Mate describes a system for locating a marker in a subject utilizing magnetic flux induced by the marker in response to an excitation source as in steps 1) and 2) of claim 11. The Examiner acknowledged that Mate does not describe discarding corrupted inputs as in step 3) of method claim 11 and receiver claim 1. However, the Examiner found that this step or receiver function would have been obvious to persons of ordinary skill in the art based on Mate's teachings.

Appellants contend that Mate does not disclose or suggest creating a "subset" of inputs by discarding corrupted inputs. The issue in this rejection is therefore whether Appellants established that the Examiner erred in determining that it would have been obvious to the ordinary skilled worker

to have modified by Mate's system by enabling it to discard marker signal inputs corrupted by a radiation source.

Principles of Law

"During [patent] examination, the examiner bears the initial burden of establishing a *prima facie* case of obviousness." *In re Kumar*, 418 F.3d 1361, 1366 (Fed. Cir. 2005).

To establish obviousness under 35 U.S.C. § 103, the following factors must be taken into consideration: (a) the scope and contents of the prior art; (b) the differences between the prior art and the claimed subject matter; (c) the level of skill in the pertinent art; and (d) evidence of secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). In making an obviousness determination, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Findings of Fact

- 1. Mate describes a method for locating and tracking the position of a target tissue in a body to determine where to deliver radiation (Abstract; 1: \P 1).
- 2. Markers are placed relative to a target, such as a tumor, in a body $(1: \P 9)$. The markers are excited by an external "excitation source" to produce an identifiable signal (id.). For example, the markers respond to excitation from an "excitation source" by resonating magnetic flux which is detected and then utilized to determine the marker's position relative to the radiation source $(3: \P \P 3, 35-39, \& 45)$.

- 3. A sensor array is provided to detect the marker signals and determine the actual location of the markers relative to the targeted tumor and radiation source (1: $\P\P$ 9-10).
- 4. Mate teaches that the "marker signal may be separated from the signal generated by the excitation source 32 via signal processing software or electronics in a number of ways." $(5: \P 53.)$
- 5. Mate describes turning the excitation source off "to allow for measurement of the marker response without interference by the signal from the excitation source"; leaving the excitation source on, but "out of phase" with the marker signal; and continuously varying the excitation source to maximize excitation of the marker signal while "minimizing or eliminating unwanted excitation signal." $(5: \P 53.)$
- 6. There is no dispute that Mate describes a receiver with a sensor as in claim 1 and teaches steps 1) and 2) of claim 11.
- 7. However, Mate does not describe a processor which is for discarding those marker signals "acquired when a therapeutic radiation source is active" as recited in claim 1 nor "discarding corrupted [marker signal] inputs subject to interference from said therapeutic radiation source . . . to create a subset of . . . inputs" as in claim 11.
- 8. Mate also does not teach that the therapeutic radiation source is able to corrupt marker signal inputs as recited in claims 1 and 11.

Analysis

The issue in this rejection boils down to whether the Examiner articulated adequate reasoning to have modified Mate's system by discarding those marker signal inputs which are acquired and subject to

interference when a therapeutic radiation source is active as required by claims 1 and 11. Citing Mate's teaching that the marker signal may be separated from the excitation source (FF4), the Examiner reasoned:

Regardless of whether the source is the actual excitation source or a therapeutic source, it would be obvious to one of skill in the art to remove erroneous data from a localization signal in order to localize the target correctly, especially when patient safety is a concern, such as minimizing collateral damage to healthy tissue surrounding the target (paragraph 35).

(Ans. 3-4.)

The Examiner has not established that the claimed subject matter would have been obvious to persons of ordinary skill in the art at the time the invention was made. The Examiner did not show that the skilled worker would have recognized that the marker signals were corrupted by the therapeutic radiation source. As explained by Appellants, the Examiner "has failed to articulate a reasoned statement for why someone skilled in the art would know that [the marker signal] data was corrupted" (App. Br. 16). The Examiner did not supply evidence "that one of ordinary skill would know to include inputs gathered when the therapeutic radiation source was not interfering with the receiver and discard inputs when the therapeutic radiation source was interfering." (Ans. 21). It was assumed by the Examiner that marker signals, received when the radiation source was active, constituted "erroneous data" (Ans. 3-4), but no evidence or reasoning was provided to show that persons of ordinary skill in the art would have recognized that the radiation would adversely affect the marker signal (see FF8).

The Examiner concluded that "[i]f the target, e.g., the marker, cannot properly be localized due to excessive noise (from whatever source), it will"

Application 10/750,164

not be possible to correctly align the radiation source with the target (Ans.

5). The Examiner asserted that Mate recognized this problem and confronted "these issues in paragraphs 53 and 54." (*Id.*)

Paragraph 53 of Mate addresses how to separate the marker signal from the signal arising from the excitation source. Paragraph 54 describes how to locate the target relative to the marker and coordinate system. There is no statement in these paragraphs that noise "from whatever source" be eliminated. The only signals that are addressed are those from the marker and excitation source. The Examiner's statements are not factually supported by the Mate disclosure.

The Examiner also stated:

Regarding the same issue of excitation source versus therapeutic radiation source it is noted that the excitation source is a form of radiation. The system and method disclosed by Mate is therapeutic. Therefore, the Examiner interpreting a "therapeutic radiation source" broadly includes the excitation source as a therapeutic radiation source because without localizing the marker within the patient the therapy provided by Mate could not function properly. Therefore, the excitation source is an integral portion of the therapy process and can, and has been, interpreted as a therapeutic radiation source.

(Ans. 7.)

There is no factual basis in Mate to draw the conclusion made by the Examiner. Mate specifically refers to radiation, excitation, and marker signals. In paragraph 53, Mate describes separating excitation and marker signals. There is no evidence that the Mate considered the excitation signal from the excitation source to be part of the therapeutic radiation; Mate discusses and addresses them individually as separate components of the system.

OBVIOUSNESS OVER MATE AND ACKER

Claims 3, 8, and 13 stand rejected under 35 U.S.C. § 103(a) as obvious over Mate and Acker (Ans. 4).

Acker is cited by the Examiner for its teaching of a filter to remove undesirable noise (Ans. 4). This reference does not make up for the deficiencies found in the Mate patent. For this reason, we are compelled to reverse the rejection.

CONCLUSION OF LAW & SUMMARY

The Examiner erred in determining that it would have been obvious to the ordinary skilled worker to have modified by Mate's system by enabling it to discard marker signal inputs corrupted by a therapeutic radiation source.

The obviousness rejections of 1, 2, 4-7, 9-12, 14, and 15 over Mate and claims 3, 8, and 13 over Mate and Acker are reversed.

REVERSED.

Appeal 2009-003286 Application 10/750,164

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